



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0350]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Tobacco Retailers on Tobacco Retailer Training Programs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the guidance entitled "Tobacco Retailer Training Programs."

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

<http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2010-D-0350 for "Guidance for Tobacco Retailers on Tobacco Retailer Training Programs." Received comments will be placed in the docket and, except for those submitted as "Confidential

Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Information Request Regarding Guidance for Tobacco Retailers on Tobacco Retailer Training Programs--OMB Control Number 0910-0745--Extension

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) does not require retailers to implement retailer training programs. However, the statute does provide for lesser civil money penalties for violations of access, advertising, and promotion restrictions of regulations issued under section 906(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)), as amended by the Tobacco Control Act, for retailers who have implemented a training program that complies with standards developed by FDA for such programs. FDA intends to issue regulations establishing standards for approved retailer training programs. In the interim, the guidance is intended to assist tobacco retailers in implementing effective training programs for employees.

The guidance discusses the elements that should be covered in a training program, such as: (1) Federal laws restricting the access to, and the advertising and promotion of, cigarettes and smokeless tobacco products; (2) the health and economic effects of tobacco use, especially when the tobacco use begins at a young age; (3) written company policies against sales to minors; (4) identification of the tobacco products sold in the retail establishment that are subject to the Federal laws prohibiting their sale to persons under the age of 18; (5) age verification methods; (6) practical guidelines for refusing sales; and (7) testing to ensure that employees have the required knowledge. The guidance recommends that retailers require current and new employees to take a written test prior to selling tobacco products and that refresher training be provided at least annually and more frequently as needed. The guidance recommends that retailers maintain certain written records documenting that all individual employees have been trained and that retailers retain these records for 4 years in order to be able to provide evidence of

a training program during the 48-month time period covered by the civil money penalty schedules in section 103(q)(2)(A) of the Tobacco Control Act.

The guidance also recommends that retailers implement certain hiring and management practices as part of an effective retailer training program. The guidance suggests that applicants and current employees be notified both verbally and in writing of the importance of complying with laws prohibiting the sales of tobacco products to persons under the age of 18 and that they should be required to sign an acknowledgement stating that they have read and understand the information. In addition, FDA recommends that retailers implement an internal compliance check program and document the procedures and corrective actions for the program.

FDA's estimate of the number of respondents in tables 1 and 2 of this document is based on data reported to the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA). According to the fiscal year 2009 Annual Synar Report, there are 372,677 total retail tobacco outlets in the 50 States, District of Columbia, and 8 U.S. territories that are accessible to youth (meaning that there is no State law restricting access to these outlets to individuals older than age 18). Inflating this number by about 10 percent to account for outlets in States that sell tobacco but are, by law, inaccessible to minors results in an estimated total number of tobacco outlets of 410,000. We assume that 75 percent of tobacco retailers already have some sort of training program for age and identification verification. We expect that some of those retailer training programs already meet the elements in the guidance, some retailers would update their training program to meet the elements in the guidance, and other retailers would develop a training program for the first time. Thus, we estimate that two-thirds of tobacco retailers would develop a training program that meets the elements in the guidance (66 percent of 410,000 = 270,600).

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Develop training program	270,600	1	270,600	16	4,329,600
Develop written policy against sales to minors and employee acknowledgement	270,600	1	270,600	1	270,600
Develop internal compliance check program	270,600	1	270,600	8	2,164,800
Total					6,765,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden¹

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeper	Total Hours
Training program	270,600	4	1,082,400	0.25 (15 minutes)	270,600
Written policy against sales to minors and employee acknowledgement	270,600	4	1,082,400	0.10 (6 minutes)	108,240
Internal compliance check program	270,600	2	541,200	0.5 (30 minutes)	270,600
Total					649,440

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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